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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/787,893 | 04/26/2001 | Marek Naruszewicz | 204742US0PCT | 5028 |

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| EXAMINER |
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MARX, IRENE

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| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 03/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/787,893

Applicant(s)
Naruszewicz

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 14, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) 5 and 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7,8 20) ☐ Other: _____

Applicant's election with traverse of Group I, claims 1-4, 6 and 11-14 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the Office has not applied the same standard of unity of invention as the International Preliminary Examination Authority. The Authority did not take the position that unity of invention was lacking. It is noted that the decision of in PCT application is not binding to U.S. practice.

Furthermore, applicants' reasoning is not found persuasive because the inventions of groups I-VI do not match a permitted category as PCT Rule 13.2 does not provide for multiple methods or products in one category. More than two patentably distinct processes i.e., the use of various bacterial strains for various purposes are claimed. As to the lack of a "special technical features" as defined in Rule 13.2, applicants state that the lack of contribution over the prior art constitutes a conclusion. Yet, as noted, Toba *et al.* demonstrates that the use of bacterial strains, such as *Lactobacillus*, to reduce the level of oxidative stress factors and/or level of reactive oxygen in mammals is known (See, e.g., Abstract). In addition, Bengmark *et al.*, col. 11; Adlerberth *et al.*, col. 1-2 and col. 15-17 teach the use of strain *Lactobacillus plantarum* 299v and other strains in the prophylaxis/treatment of diseases caused by bacteria, which include at least inflammatory diseases, encompassed by the present invention.

Therefore, the uses recited lack those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL. .

Claims 5 and 7-10 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 6 provide for the use of a bacterial strain, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. The claims do not indicate the mode or dose of administration. Is it intravenous?

Claims 1-4 and 6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 1 is vague, indefinite and confusing in the recitation of "significant increase in the fecal concentration of propionic acid" and of "reduction of level of oxidative stress factors in blood". The "increase" and "reduction" intended cannot be readily ascertained, since the baseline amount is not indicated. In addition, the nature of the intended "oxidative stress factors in blood" is not readily apparent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Toba et al..

The claims appear to be directed to the use of bacterial strains, including *L. plantarum* and *Propionibacterium* to reduce oxidative stress factors in blood.

The reference discloses the use of bacterial strains, including *L. plantarum* to reduce oxidative stress factors in blood (See, e.g., Test Examples 1-5). The fecal increase in propionic acid is an inherent property of the microbe.

Therefore, the invention as claimed is anticipated by the reference.

Claims 1-4, 6 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bengmark et al.

The claims appear to be directed to the use of bacterial strains, including *L. plantarum* and *Propionibacterium* to reduce oxidative stress factors in blood.

The reference discloses the administration of bacterial strains, including *L. plantarum* 299 and 299v to patients. See, e.g., Table 1, wherein 299v is reported as A1. The reduction of oxidative stress factors in blood and the fecal increase in propionic acid are inherent properties of the administration of the microbe to the patient.

Therefore, the invention as claimed is anticipated by the reference.

Claims 1-4, 6 and 11-14 are rejected under 35 U.S.C. 102^b(e) as being anticipated by Bengmark et al.

The claims appear to be directed to the use of bacterial strains, including *L. plantarum* and *Propionibacterium* to reduce oxidative stress factors in blood.

The reference discloses the administration of bacterial strains, including *L. plantarum* 299v to patients. See, e.g., Col. 4, lines 6-9 wherein 299v is reported to be administered. The reduction of oxidative stress factors in blood and the fecal increase in propionic acid are inherent properties of the administration of the microbe to the patient.

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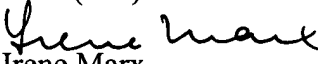
Therefore, the invention as claimed is anticipated by the reference.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196 .


Irene Marx
Primary Examiner
Art Unit 1651